DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 19, 2015

Biogennix, LLC
% Ms. Meredith May
Empirical Consulting
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K141798
Trade/Device Name: Sypher Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: January 21, 2015
Received: January 23, 2015

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141798

Device Name
Sypher Spacer System

Indications for Use *(Describe)*
The Sypher Spacer System is an intervertebral body fusion system indicated for intervertebral body fusion procedures in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use with autogenous bone graft at one or two contiguous levels of the lumbar spine (from L2 to S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation to facilitate fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(K) SUMMARY

Submitter's Name:	Biogennix, LLC
Submitter's Address:	18011 Sky Park Circle, Suite M Irvine, CA 92614
Submitter's Telephone:	949.253.0994
Contact Person:	Meredith L. May, MS Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	01-Jul-14
Trade or Proprietary Name:	Sypher Spacer System
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Device Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX, OVD
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Sypher Spacer System implants are cylinder shaped blocks made of PEEK Optima® LT1 (Polyether ether ketone per ASTM F2026), with tantalum alloy radiological position markers (per ASTM F560), titanium alloy self-drilling and self-tapping bone screws (per ASTM F136), and titanium alloy cage lock assemblies (per ASTM F136).

The implants are available in a variety of footprints, heights and lordotic angles. The shape of the Sypher product allows for a larger implant (height and width) to be used allowing for more surface area contact. The Sypher Spacer System is offered in a closed graft space design. The implants incorporate integrated anterior screw holes to allow for medial placement of screws, as well as a titanium alloy cage lock assembly for securing the screws once in place. Additional or other supplemental fixation may be used, as patient needs dictate. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and to prevent movement of the implants. The Sypher Spacer System is intended to be used with autologous bone graft.

INDICATIONS FOR USE

The Sypher Spacer System is an intervertebral body fusion system indicated for intervertebral body fusion procedures in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use with autogenous bone graft at one or two contiguous levels of the lumbar spine (from L2 to S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation to facilitate fusion.

TECHNOLOGICAL CHARACTERISTICS

Biogennix, LLC Sypher Spacer System

Sypher Spacer System is made from PEEK Optima® LT1, Tantalum, and Titanium alloy that conforms to ASTM F2026, ASTM F560, and ASTM F136, respectively. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are similar or identical between the subject and predicates:

- Intended Use
- Materials of manufacture
- Structural support mechanism
- Indications for Use

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K120031	Chesapeake® Anterior-Lumbar Stabilization System	K2M	Primary
K100089	T-PAL Spacer	Synthes	Additional
K103034, K130913	Apache™ Lateral Lumbar Interbody Fusion System	Genesys Spine	Additional

PERFORMANCE DATA

The Sypher Spacer System has been tested in the following test modes:

- Static axial compression bending per ASTM F2077-11
- Static compressive shear per ASTM 2077-11
- Static subsidence per ASTM F2267-04 and ASTM 2077-11
- Dynamic axial compression per ASTM 2077-11
- Dynamic compressive shear per ASTM 2077-11
- Expulsion per ASTM Draft Standard F-04.25.02.02

The results of this non-clinical testing show that the strength of the Sypher Spacer System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Sypher Spacer System is substantially equivalent to the predicate device.